

ARIXTRA solution for injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARIXTRA?

ARIXTRA contains the active ingredient fondaparinux sodium. ARIXTRA is used to treat or prevent blood clots, as well as to treat certain types of heart attacks and angina.

For more information, see Section [1. Why am I using ARIXTRA?](#) in the full CMI.

2. What should I know before I am given ARIXTRA?

Do not use if you have ever had an allergic reaction to fonaparinux sodium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ARIXTRA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARIXTRA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is ARIXTRA given?

- The usual dose of ARIXTRA is 2.5 mg given once a day, starting after your operation. It may be given for up to 31 days.
- It is usually given to you as a subcutaneous injection, an injection under the skin, by a doctor or nurse. The first dose may be given intravenously, into the vein, for certain types of heart attack.
- You may be taught how to give yourself the subcutaneous injection. Instructions are attached at the end of the leaflet.

More instructions can be found in Section [4. How is ARIXTRA given?](#) in the full CMI.

5. What should I know while using ARIXTRA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARIXTRA.• Tell your doctor immediately if you develop pain or swelling in the legs, or chest pain or difficulty breathing.
Things you should not do	<ul style="list-style-type: none">• Do not use ARIXTRA to treat any other complaints unless your doctor or pharmacist tells you to.• Do not give ARIXTRA to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• ARIXTRA will normally be stored in the pharmacy or on the hospital ward.• It should be kept at room temperature where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ARIXTRA?](#) in the full CMI.

6. Are there any side effects?

Common side effects of using ARIXTRA include bleeding, oozing of fluid from the wound, unusual tiredness, weakness or drowsiness, fever, nausea or vomiting, indigestion or gastritis, low blood pressure, dizziness or confusion, difficulty sleeping, pain or skin reactions at the injection site, urinary tract infection, difficulty or pain when passing urine, diarrhoea or constipation, headache, coughing, or swelling (oedema). These common side effects are usually mild.

Serious side effects of using ARIXTRA include significant bleeding, and an allergic reaction. Signs of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, and rash, itching or hives on the skin. There may also be other side effects which may only be found by tests that your doctor performs. These include changes in liver function or enzymes, and blood disorders e.g. decreased or abnormal blood platelets, clotting disorders or excess bilirubin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARIXTRA solution for injection

Active ingredient: *fondaparinux sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARIXTRA.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARIXTRA.

Where to find information in this leaflet:

- [1. Why am I using ARIXTRA?](#)
- [2. What should I know before I am given ARIXTRA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ARIXTRA given?](#)
- [5. What should I know while using ARIXTRA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARIXTRA?

ARIXTRA contains the active ingredient fondaparinux sodium.

ARIXTRA is used to prevent blood clots forming in patients who are recovering from orthopaedic or abdominal surgery. Blood clots, such as deep venous thrombosis, or DVT, can occur in patients who are confined to bed after hip or knee surgery. ARIXTRA is also used to treat blood clots once they have formed.

ARIXTRA is also used to treat some types of heart attacks and severe angina, a pain caused by narrowing of the arteries in the heart.

Ask your doctor if you have any questions about why ARIXTRA has been prescribed for you.

Your doctor may have prescribed ARIXTRA for another reason.

2. What should I know before I am given ARIXTRA?

Warnings

You should not be given ARIXTRA if:

- you have any of the following medical conditions:**
 - you are bleeding excessively
 - you have severe kidney disease
 - you have acute bacterial endocarditis (an infection of the heart)
- you are allergic to fondaparinux, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.

- the expiry date printed on the pack has passed.**
- the packaging is torn or shows signs of tampering.**

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - a stomach ulcer
 - bleeding disorders
 - recent bleeding inside the head
 - recent surgery on the brain, eye, or spinal column
 - moderate or severe kidney disease or severe liver disease
 - heparin induced thrombocytopenia (low platelet count).
- take any medicines for any other condition
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- have had any allergy to latex – the syringe needle shield contains latex
- are elderly or have a low body weight (less than 50 kg) as you may be at increased risk of bleeding if you are given ARIXTRA.
It is recommended that your doctor monitors your blood platelets at the beginning and end of your treatment with ARIXTRA.
- if you are going to have a stent inserted into your heart.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or intend to become pregnant.

ARIXTRA is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved of using ARIXTRA in pregnancy.

You should not use ARIXTRA if you are breastfeeding or plan to breastfeed.

It is not known whether ARIXTRA passes into human breast milk.

Use in children

This medicine should not be used in children under the age of 17 years.

Safety and effectiveness in children younger than 17 years have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ARIXTRA may interfere with each other.

4. How is ARIXTRA given?

How much is given

The usual dose of ARIXTRA is 2.5 mg given once a day, starting after your operation. ARIXTRA may be given for up to 31 days.

How it is given

- The injections can be given by a doctor or a nurse, or you may be taught how to give the subcutaneous injections to yourself.
- Instructions on how to use the ARIXTRA syringe subcutaneously are given at the end of this leaflet.
- ARIXTRA is given to you as a subcutaneous injection, an injection just under the skin. To treat some types of heart attack, the health professional only may give the first dose intravenously, into a vein.
- ARIXTRA should not be given as an intramuscular injection, an injection into the muscle.

If you forget to use ARIXTRA

ARIXTRA should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much ARIXTRA

If you think that you have used too much ARIXTRA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ARIXTRA?

Things you should do

If you are about to be started on any new medicine, tell your doctor, dentist, or pharmacist that you are using ARIXTRA.

Tell your doctor immediately if you:

- develop pain or swelling in the legs.
- develop chest pain or difficulty in breathing. These may be signs that a blood clot has formed.
- have an epidural or spinal anaesthesia (a pain killing injection around the spinal cord) and you experience back pain, numbness or weaken in the legs, or problems with bowel or bladder function.

Things you should not do

- **Do not use ARIXTRA to treat any other complaints unless your doctor or pharmacist tells you to.**
- **Do not give ARIXTRA to anyone else, even if they have the same condition as you.**

Looking after your medicine

- ARIXTRA will normally be stored in the pharmacy or on the hospital ward.
- It should be kept at room temperature where the temperature stays below 25°C.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• bleeding (for example from an operation site, an existing stomach ulcer, nosebleed, gums, blood in urine, coughing up blood, bleeding from eyes, bleeding in joint spaces, internal bleeding in uterus)• localised collection of blood (in any organ/body tissue)	<p>Speak to your doctor if you have any of these less serious side effects.</p> <p>Do not stop using ARIXTRA without first</p>

<ul style="list-style-type: none"> • anaemia (a reduction in the number of red blood cells) • bruising oozing of fluid from the wound • unusual tiredness, weakness, or drowsiness • fever • nausea or vomiting • indigestion or gastritis • low blood pressure • fainting or vertigo • dizziness or confusion or anxiety • difficulty sleeping • pain, swelling or skin reactions at the injection site • wound infection • chest pain • pain around the upper part of the stomach or heartburn • leg pain or stomach pain • rash or itchy skin • increase in bilirubin (a substance produced by the liver) in the blood • increase in the amount of non-protein nitrogen in the blood • reduction in potassium in your blood • itching sensation on the skin • urinary tract infection • difficulty or pain when passing urine • diarrhoea or constipation • indigestion • headache • coughing • swelling (oedema) • shortness of breath • flushing of the skin. 	<p>talking to your doctor or pharmacist.</p>
---	---

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What ARIXTRA contains

Active ingredient (main ingredient)	• fondaparinux sodium 2.5 mg/ 0.5 mL pre-filled syringe.
Other ingredients (inactive ingredients)	• sodium chloride • water for injections.

ARIXTRA contains no antimicrobial preservative.

Do not take this medicine if you are allergic to any of these ingredients.

What ARIXTRA looks like

ARIXTRA comes as a pre-filled glass safety syringe containing a clear to practically clear and colourless liquid. Available in pack sizes of 2 pre-filled syringes.

Australian Registration number: AUST R 80279

Who distributes ARIXTRA

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St. Leonards NSW 2065
Australia

This leaflet was revised in November 2025.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • allergic reaction. Signs include shortness of breath, wheezing, or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, or rash, itching or hives on the skin. • significant bleeding • internal bleeding in the brain, liver or abdomen. 	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Some side effects may only be identified by tests performed by your doctor, such as:

- blood disorders e.g. decreased or abnormal blood platelets, clotting disorder, or excess bilirubin
- changes in liver function or liver enzymes.

Method of administration

Arixtra is administered by **subcutaneous injection (an injection just under the skin)**. Arixtra is for single use in one patient only. Discard any residue.

The solution should be inspected visually for particles and discoloration prior to administration. If present, do not proceed with the injection.

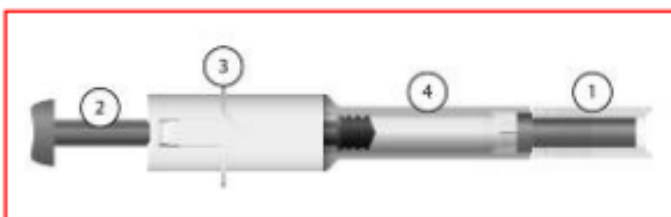
Subcutaneous administration

The sites of subcutaneous injection should be on the fatty tissues on the abdominal area. It is important to alternate between the left and the right sides. To avoid the loss of medicinal product when using the pre-filled syringe do not expel the air bubble from the syringe before injection. The whole length of the needle should be inserted between the thumb and forefinger (see figures 2 and 3). The skin fold should be held throughout the injection.

Arixtra is intended for use under a physician's guidance. Patient's may self-inject only if their physician determines that it is appropriate, and with medical follow-up as necessary. Proper training in **subcutaneous injection** technique should be provided. Instructions for self-administration **subcutaneously** are included below.

The parts of the syringe with an automatic needle protection system are:

1. Needle shield
2. Plunger
3. Finger-grip
4. Security sleeve



To use the Arixtra syringe, remove the needle shield, by first twisting it and then pulling it straight off (figure 1).

Discard the needle shield.



Figure 1

For **subcutaneous** administration:

Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger during the entire injection (figure 2).



Figure 2

Insert the full length of the needle perpendicularly (at an angle of 90°) into the skin fold (figure 3).



Figure 3

Inject ALL of the content of the syringe by pressing down on the plunger as far as it goes (figure 4), and then release it: the needle will withdraw automatically from the skin into a security sleeve and then will be locked permanently (figure 5).



Figure 4



Figure 5

Discard the used syringe in a safe manner by using a sharps disposal container. This is usually available at the local community pharmacy.